



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,821	09/22/2003	Valerie De Poilly	230016US0	7262
22850	7590	04/06/2006	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.			ALSTRUM ACEVEDO, JAMES HENRY	
1940 DUKE STREET			ART UNIT	
ALEXANDRIA, VA 22314			PAPER NUMBER	

1616

DATE MAILED: 04/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/665,821

Applicant(s)

DE POILLY, VALERIE

Examiner

James H. Alstrum-Acevedo

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 17-18 and 22-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 19-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/22/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-27 are pending.

Election/Restrictions

Applicant's election with traverse of Group I (claims 1-16 and 19-21) in the reply filed on January 30, 2006 is acknowledged. The traversal is on the ground(s) that the Examiner has not carried out the burden of providing sufficient reason and/or examples to support a restriction requirement of the instant claims. This is not found wholly persuasive because the claims of Groups I-III are clearly drawn to compositions reciting distinctly different benzylidenecamphor derivatives. Although the compounds of formulae I-III have structural similarities, these formulae represent three different kinds of subgenus of the generic class of benzylidenecamphor compounds. A person of ordinary skill in the art would readily recognize that compounds having significantly different structural components, as evidenced by substituent Z in formula I and the heterocyclic substituent on the phenyl ring of formula III, would be expected to have different mechanisms of action, biological activities, solubilities, degrees of hydrophilicity and/or hydrophobicity, polarity, etc. Regarding the differences between groups IV and V, the Examiner has found the Applicant's arguments persuasive, and Groups IV-V are hereby combined into a new Group IV, comprising claims 1 and 22-26. Groups I-III remain unchanged and Group VI is now Group V. Finally, as noted in the previous communication from the office regarding the instant application:

Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the**

Art Unit: 1616

limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The requirement is still deemed proper and is therefore made FINAL.

Claims 17-18, and 22-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on January 30, 2006.

Specification

The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner

Art Unit: 1616

representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The use of the trademarks MEXORYL SX[®] (pg. 9, line 17), MEXORYL SL[®] (pg. 10, line 18), EUSOLEX 22[®] (pg. 14, line 2), MIGLYOL[®] (pg. 15, line 23), PARLEAM[®] (pg. 16, line 14), ARLACEL[®] (pg. 18, line 23; pg. 20, line 3), GRILLOCOSE[®] (pg. 21, line 4), and EMULGADE[®] (pg. 22, line 1) have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. Applicant's cooperation is requested in correcting the use of any other trademarks of which applicant may become aware in the specification.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 9-14, and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Tanner et al. (U.S. Patent No. 6,024,942; IDS).

Tanner discloses skin care compositions, comprising: (a) from about 0.1% to about 30% of a sunscreen active, (b) from about 0.5% to about 20% of a hydrophobic, structuring

Art Unit: 1616

agent, (c) from about 0.2% to about 10% of a hydrophilic surfactant, (d) from about 0.1% to about 5% of a thickening agent, (e) from about 0.1% to about 25% of a skin lightening agent and (f) water. These compositions are useful for providing (i) protection to human skin from the harmful effects of ultraviolet radiation and (ii) a skin lightening benefit (abstract). Skin care compositions are cosmetic/dermatologic compositions.

Tanner discloses that his skin care compositions are stable, cosmetic, aqueous-containing compositions having gel networks, liquid crystalline phases, or both (col. 1, lines 12-13).

Tanner discloses that the skin care compositions are in the form of oil-in-water (O/W) emulsions useful for topical application to the skin (col. 3, lines 20-21, 25-26). Suitable sunscreen agents include organic compounds and their salts as well as inorganic particulate materials, including 2-phenyl-benzimidazole-5-sulfonic acid (col. 4, lines 8-12, 23-25, 46-47). Suitable thickening agents include cross-linked vinyl ether/maleic anhydride copolymers. A preferred copolymer is formed from methyl vinyl ether and maleic anhydride, wherein the copolymer has been crosslinked with decadiene. An example of such a copolymer is the commercially available copolymer, STABILEZE® (col. 16, lines 19-34). Skin lightening agents comprise from about 0.001% to about 40% of the composition (col. 16, lines 55-57). Suitable skin lightening agents include L-ascorbic acid and derivatives thereof, including magnesium ascorbyl phosphate (col. 17, lines 2-5; col. 19, lines 10-12). The composition comprises from about 25% to about 99.1% water (col. 19, lines 33-35).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3 and 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanner et al. (U.S. Patent No. 6,024,942; IDS) in view of Prencipe et al. (U.S. Patent No. 5,385,729).

The disclosures/teachings of Tanner have been set forth above.

Tanner lacks the express teaching of a polymer wherein the maleic anhydride units are hydrolyzed in the form of alkaline salts, the mole fraction of maleic anhydride within the polymer structure, and styrene/maleic anhydride copolymers.

Prencipe teaches a **personal care composition** in the form of a hair or skin-treating gel containing an amount of a synthetic linearly viscoelastic cross-linked polymeric thickening agent, especially **a cross-linked methyl vinyl ether/maleic anhydride copolymer**, effective to render the composition linearly viscoelastic, and a method of promoting personal care by

Art Unit: 1616

applying an effective amount of the composition to the hair or skin (abstract). Person care compositions are also cosmetic/dermatological compositions.

Prencipe teaches that his invented composition enables the provision in aqueous gel form of substantially all types of **personal care or cosmetic compositions** for topical treatment of, or **application to, hair and skin** (col. 2, lines 23-27).

Prencipe teaches that in a preferred embodiment, the required crosslinked polymer is derived from a synthetic anionic polymeric polycarboxylate, many types of which are disclosed in the prior art (col. 4, lines 63-66). These synthetic anionic polymeric polycarboxylates are often per se employed in the form of their free acids or more preferably fully neutralized water-soluble or water swellable **alkali metal (e.g. potassium and preferably sodium)** or ammonium **salts**. Preferred are **1:4 to 4:1 copolymers of maleic anhydride or acid with another polymerizable ethylenically unsaturated monomer, preferably methyl vinyl ether/maleic anhydride (MVE/MA) having a molecular weight (M.W.) of about 30,000 to about 1,000,000** (col. 5, lines 3-11). Maleic acid is the hydrolyzed form of maleic anhydride. Additional operative polymeric polycarboxylates disclosed previously by Prencipe referred to U.S. Pat. No. 4,138,477 and 4,183,914, and include **copolymers of maleic anhydride with styrene** (col. 5, lines 33-36).

The following reference teachings are being provided to illustrate what is well known in the art regarding copolymers of styrene and maleic anhydride.

Odian (*Principles of Polymerization*, 3rd edition, John Wiley & Sons, Inc.: New York, 1991, pp 485-487) teaches that maleic anhydride does not homopolymerize but will readily form (very strongly) alternating copolymers with electron-donor monomers, including styrene. The

Art Unit: 1616

characteristic alternating radical polymerization of styrene and maleic anhydride monomers is a consequence of the product of the reactivity of the respective monomeric radicals being very close to zero ($r_1 r_2 = 0.006$ for styrene/maleic anhydride copolymerization (Table 6.6 and 1st paragraph beginning on page 487 of Odian). A perfectly alternating copolymer prepared from two different monomers would consist of a 50:50 mixture of both monomers, which would occur when the product, $r_1 r_2$, equals zero.

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Tanner and Prencipe, because both inventors teach cosmetic formulations comprising maleic anhydride polymer thickeners that could be applied to the skin. A person of ordinary skill would have had a reasonable expectation of success upon combining the teachings of Tanner and Prencipe, because both inventors teach personal care compositions intended for application to the skin and comprising maleic anhydride copolymer thickeners. Regarding the use of a 50:50 styrene/maleic anhydride copolymer, it would have been readily apparent to a skilled artisan that styrene/maleic anhydride copolymers would be comprised of a 50:50 mixture of these two polymers, because maleic anhydride does not homopolymerize and it is well known that it forms alternating copolymers in radical polymerizations with styrene co-monomer. Furthermore, notwithstanding the strongly alternating nature of a radical polymerization of styrene and maleic anhydride, a skilled artisan would have been capable of adjusting monomer feed ratios and reaction temperature to ensure that reaction product was a copolymer comprised of a 50:50 mixture of styrene and maleic anhydride.

Claims 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanner et al. (U.S. Patent No. 6,024,942; IDS) in view of Lang et al. (U.S. Patent No. 5,064,641).

The teachings of Tanner have been set forth above.

Tanner lacks the teaching of compositions comprising a benzylidenecamphor derivative of formula (I) or specifically, benzene-1,4-bis(3-methylidenecamphor-10-sulfonic acid).

Lang teaches **polyvalent metal salts of sulfonated derivates of benzylidenecamphor** and their use for protecting the skin against ultraviolet radiation, wherein Lang's compounds of formula (I) have X_1 equal to a Y_1 derivative and X_2 being a hydrogen atom (title and abstract). The chemical structures of the compounds taught by Lang encompass the applicant's formula (I) compounds, depicted in claim 15 of the instant application, and the species recited in claim 16. Lang's formula (III) (col. 3, lines 1-5) encompasses the applicant's formula (I) in claim 15 and the species recited in claim 16.

Lang teaches that his invented benzylidenecamphor derivatives are used as sunscreens in cosmetic compositions (col. 1, lines 7-10), wherein the **cosmetic composition** may have one of a variety of forms, including a suspension or **emulsion** (e.g. cream or milk). The cosmetic compositions may also comprise adjuvants customarily used, such as **thickeners**, emollients, humectants, surfactants, preservatives, antifoams, fragrances, oils, waxes, lanolin, propellants, colorants, and/or pigments. These camphor derivatives are present in amounts ranging from between 0.25 and 3% by weight of the total composition (col. 4, lines 2-32).

Lang teaches the preparation of the camphor derivative salts in Example I.

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Tanner and Lang, because Tanner teaches skin care compositions comprising a sunscreen active. The camphor derivatives taught by Lang are sunscreen actives. A skilled artisan would have had a reasonable expectation of success upon combining the prior art teachings of Tanner and Lang, because Lang's compositions are sunscreen active agents. Although Lang teaches metal salts of the camphor derivatives, these would have been obvious over the neutral forms of said derivatives, because they are made by the addition magnesium chloride hexahydrate to an aqueous solution of the neutral salt.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 14-16, and 19-21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 8, 9, and 11-12 of U.S. Patent No. 5,064,641 (USPN '641) in view of Tanner et al. (U.S. Patent No. 6,024,942). Although the claims are not the same they are obvious over one another and overlapping in scope. Both claim sets recite compositions comprising sunscreen agents having a sulphonic function, such as the compounds of formula (I) in the instant application and those of Lang's formulae (I) and (III). Both applications also recite compositions in the form of an emulsion and compositions having overlapping ranges of sunscreen active agents. One difference between the claims of USPN '641 and those of the instant application is that the claims of USPN '641 lack at least one metal salt of phosphorylated ascorbic acid and at least one maleic anhydride polymer. Both phosphorylated ascorbic acid and maleic anhydride polymer are adjuvants one could add to a cosmetic/dermatological preparation. The deficiencies of USPN '641 are cured by the teachings of Tanner, who teaches cosmetic compositions comprising magnesium ascorbyl phosphate (a skin lightening agent) and vinyl ether/maleic anhydride copolymers (a thickening agent). Thickening agents (i.e. thickeners) are common adjuvants used in the cosmetic art. Therefore, the claims 1, 14-16, and 19-21 of the instant application are obvious over claims 1, 5, 8, 9, 11, and 12 of USPN '641. This instant obviousness type double-patenting rejection is proper, because USPN '641 has the same assignee as the instant application.

Conclusion

The specification is objected. Claims 1-16 and 19-21 are rejected. No claims are allowed.

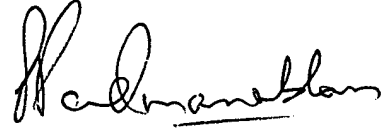
Art Unit: 1616

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James H. Alstrum-Acevedo, Ph.D.
Examiner



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER